3685553-3-00-01

COVANCE

by user - facilities distributors and
cturers for MANDATORY reporting

FDA Facsimile Approval 6/13/96

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Mfr report # 8287900

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event: / or Date of birth:	3. Sex	4. Weight
UNK 8287900 in confidence	16	☑ female ☐ male	UNK lbs / or kg

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

☐ death (mo/day/yr) ☐ disability
☐ life-threatening ☐ congenital anomaly
☑ hospitalization-initial or prolonged ☐ required intervention to prevent permanent impairment/damage
☐ other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
03/05/2001	03/13/2001

5. Describe event or problem

Information has been received from an emergency room nurse via Pittsburgh Poison Center regarding a 16-year-old female consumer who had ingested an unknown amount of Aleve and 20 gms of Tylenol on 05-Mar-2001. The consumer began vomiting and continued for 2 days. She was evaluated in the emergency room on 08-Mar-2001 for complaints of bilateral flank pain. Her urine was positive for blood and elevated protein. She appeared dehydrated. She was treated with intravenous fluids, 17 doses of N-acetylcysteine and Reglan (metoclopramide hydrochloride) as needed. On 08-Mar-2001 at 7 PM, lab test results included an ALT (alanine transaminase) level of 81 U/mL, an AST (aspartate transaminase) level of 54 U/mL, drug screen, APAP (acetaminophen) and ASA (acetylsalicylic acid) levels were all negative. On 09-Mar-2001, an ALT level was 48 U/mL and an AST level was 26 U/mL. Medical history and concomitant therapy were not provided. If additional information is obtained, it will be forwarded.

6. Relevant tests/laboratory data, including dates

08-Mar-2001: urine was positive for blood and elevated protein level. 08-Mar-2001: ALT=81 U/mL; AST=54 U/mL; drug screen, APAP and ASA levels were all negative. 09-Mar-2001:ALT=48 U/mL; AST=26 U/mL.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

None Provided

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 ALEVE. - Any Type
#2 Tylenol

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 UNK ORAL 01X	#1 03/05/2001 - 03/05/2001
#2 UNK ORAL 01X	#2 03/05/2001 - 03/05/2001

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 Unknown	#1 ☐ yes ☐ no ☑ n/a
#2 Unknown	#2 ☐ yes ☐ no ☑ n/a

6. Lot # (if known)	7. Exp. date (if known)
#1 UNK	#1 UNK
#2 UNK	#2 UNK

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☑ n/a
#2 ☐ yes ☐ no ☑ n/a

9. NDC #-for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

None Provided

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

Bayer Corporation
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

2. Phone number: (973) 254-5000

3. Report Source (check all that apply)
☐ foreign ☐ study ☐ literature ☐ consumer ☑ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other:

4. Date received by manufacturer (mo/day/yr): 03/09/2001

5. (A)NDA # 20 - 204
IND #
PLA #
pre-1938 ☐
OTC product ☑

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☑ 15-day ☐ 10-day ☐ periodic ☑ initial ☐ follow-up # 0

8. Adverse event term(s)
OVERDOSE;VOMITING;BACK PAIN;HEMATURIA;ALBUMINURIA;DEHYDRATION;SGPT INCREASED;SGOT INCREASED

9. Mfr. report number
8287900

E. Initial reporter

1. Name, address & phone #
UNK

DSS
MAR 2 1 2001

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
☑ yes ☐ no	NURSE	☐ yes ☐ no ☑ unk

FDA FACSIMILE

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

MAR 2 0 2001